

PTC/SB/08a/b (08-03)
Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1895, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Subs	stitute for form 1449A/B/F	то		Complete If Known		
				Application Number	10/750,138	
IN	<b>IFORMATIO</b>	N DI	SCLOSURE	Filing Date	December 31, 2003	
STATEMENT BY APPLICANT				First Named Inventor	David Gschneidner	
				Art Unit	N/A	
	(Use as many s	heets as	necessary)	Examiner Name	Not Yet Assigned	
Sheet	1	of	3	Attorney Docket Number	01946/100G527-US2	

			U.S. PAT	ENT DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2</sup> ( # known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
M	AA**	US-5,776,888-B1	07-07-1998	Leone-Bay et al.	
$\nabla \Gamma$	AB**	US-5,629,020	05-13-1997	Leone-Bay et al.	
	AC**	US-5,643,957	07-01-1997	Leone-Bay et al.	
	AD**	US-5,766,633	06-16-1998	Milstein et al.	
	AE**	US-5,863,944	01-26-1999	Leone-Bay et al.	
	AF**	US-5,866,536	02-02-1999	Leone-Bay ey al.	
	AG**	US-5,650,386		Leone-Bay et al.	
	AH**	US-3,795,739	03-05-1974	Birkmayer et al.	
	Al**	US-3,939,253		Bodor et al.	
	AJ**	US-4,061,466	12-06-1977	Sjoholm et al.	
	AK**	US-4,147,767	04-03-1979	Yapel	
	AL**	US-4,207,341		Hubner et al.	
	AM**	US-4,221,815	09-09-1980	Weyer et al.	
	AN**	US-4,238,506	12-09-1980	Stach, deceased et al.	
	AO**	US-4,239,754		Sache et al.	
	AP**	US-4,393,192	07-12-1983	Curatolo et al.	
	AQ**	US-4,442,090		Kakeya et al.	
7	AR**	US-4,499,299	02-12-1985	Bernstein et al.	
	AS**	US-4,462,991		Higuchi et al.	
	AT**	US-4,656,161		Herr et al.	
	AU**	US-4,654,327	03-31-1987	Teng	
	AV**	US-4,692,433		Hostetler et al.	
	AW**	US-4,757,066		Shiokari et al.	
_	AX**	US-4,835,312		Itoh et al.	
	AY**	US-4,873,087		Morishita et al.	
	AZ**	US-4,878,942	11-07-1989	Motegi et al.	
	AA1**	US-4,900,730		Miyauchi	
	AB1**	US-4,927,928	05-22-1990	Shroot et al.	
	AC1**	US-5,066,487	11-19-1991	Morelle et al.	<del> </del> -
	AD1**	US-5,352,461		Feldstein e al.	<del></del>
	ÀE1**	US-5,665,700	09-09-1997	Cho et al.	
_	AF1**	US-5,705,529		Matyus et al.	
	AG1**	US-5,447,728		Milstein et al.	
	AH1**	US-5,451,410		Milstein et al.	
	Al1**	US-5,541,155		Leone-Bay et al.	
	AJ1**	US-5,709,861		Santiago et al.	<del></del>
	AK1**	US-5,714,167		Milstein et al.	
-	AL1**	US-5,750,147		Kantor et al.	
1	AM1**	US-Re 35,862	07-28-1998	Steiner et al.	
-H	AN1**	US-5,792,451	08-11-1998	Sarubbi et al.	
4	AO1**	US-5,804,688		Leone-Bay et al.	<del></del>

Examiner Signature	Cw	Date Considered	8/	08

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sut	stitute for form 1449A/B/P	то		Complete if Known		
	_			Application Number	10/750,138	
11	<b>IFORMATIO</b>	N DI	SCLOSURE	Filing Date	December 31, 2003	
S	<b>TATEMENT</b>	BY A	APPLICANT	First Named Inventor	David Gschneidner	
				Art Unit	N/A	
	(Use as many s	heets a	necessary)	Examiner Name	Not Yet Assigned	
Sheet	2 .	of	3	Attorney Docket Number	01946/100G527-US2	

$\mathcal{L}$	<u> </u>					
I		P1**	US-5,811,127	09-22-1998	Milstein et al.	
$oldsymbol{ u}$		Q1**	US-5,876,710	03-02-1999	Leone-Bay et al.	
		R1**	US-5,879,681	03-09-1999	Leone-Bay et al.	
	A	S1**	US-5,939,381	08-17-1999	Leone-Bay et al.	
	A	T1**	US-5,958,457	09-28-1999	Santiago et al.	
	A	U1**	US-5,965,121	10-12-1999	Leone-Bay et al.	$\neg$
	A	V1**	US-5,989,539	11-23-1999	Leone-Bay et al.	П
	A	W1**	US-5,990,166	11-23-1999	Leone-Bay et al.	$\neg$
		X1**	US-6,001,347	12-14-1999	Leone-Bay et al.	
	A	Y1**	US-5,773,647	06-30-1998	Leone-Bay et al.	$\neg$
	Α	Z1	US-5,401,516	03-28-1995	Milstein et al.	
J	Α	A2	US-5,443,841	08-22-1995	Milstein et al.	П
	Α	B2**	US-4,035,507	07-12-1997	Bodor et al.	ヿ

		FOREI	GN PATENT D	OCUMENTS		
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,	oxdot
Initials*	No.	Country Code <sup>3</sup> -Number + Hind Code <sup>5</sup> (if known)	Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T°
4	BA**	EP0576941	01-05-1994			
ेर्न	BB**	EP0036145	09-23-1981			Г
	BC**	EP0365183	04-25-1990			Т
	BD**	EP0517211	12-09-1992			$\sqcap$
	BE**	EP226223	06-24-1987			
	BF**	FR4446	11-02-1966			
	BG**	GB2095994	10-13-1982			
	BH**	JP2239980	09-21-1990			Т
	BI**	JP4837819	11-14-1973			Г
	BJ**	ES369853	07-16-1971			Г
	BK**	WO8807378	10-06-1988	•		Т
	BL**	WO9747270	12-18-1997			$\vdash$
	ВМ	WO9630036	10-03-1996			$\Box$
, ,	BN	WO9736480	10-09-1997			
A	BO**	WO9929705	06-17-1999	······································		$\Box$

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. "CITE NO.: Those patent(s) or publication(s) which are marked with an double estarisk ("") next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120. "Applicant's unique citation designation number (optional). Is see Kinds Codes of USPTO Patent Documents at <a href="https://www.uspio.sog">www.uspio.sog</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as Indicated on the document under WIPO Standard ST.18 if possible. Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS									
Examiner Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.									
			Date						

Considered

Examiner Signature

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE spond to a collection of information unless it contains a valid OMB control number.

Sut	estitute for form 1449A/B/P	то		Complete if Known		
				Application Number	10/750,138	
11	NFORMATIO!	N DI	SCLOSURE	Filing Date	December 31, 2003	
S	TATEMENT	BY A	APPLICANT	First Named Inventor	David Gschneidner	
				Art Unit	N/A	
	(Use as many si	heets as	necessary)	Examiner Name	Not Yet Assigned	
Sheet	3	of	3	Attorney Docket Number	01946/100G527-US2	

9	CA**	Picciola G.: "Sintesi Di Acidi Chiazolinioici E Benzossazinonici E Studio Delle Loro Proprieta Antiniarmmatorie" IT, Societa Chimica Italiana Pavia vol 31, no. 9 pgs 655-664 and English Translation
	CB**	Chem Abs 73548-12-6 (4/1991)
	CC**	Chem Abs 70204-54-5 (4/1991)
	CD**	Chem Abs 184360 -83-342 (1975) "Solubility and disassociation constants of some alicyclic acids
	CE**	Chemical Abstract, Vol. 99(23) Abst. No. 191473h (1983)
	CF**	Riveria, Theresa M. et al. "Oral Delivery of Heparin in Combination with Sodium N-[8-2-hydroxybenzoyl)amino]caprylate: Pharmacological Considerations" Pharmaceutical Research vol 14(12) 1830-1834 (1997)
	CG**	Leone-Bay, A. et al. " The evolution of an oral heparin dosing solution" Drugs of the Future vol 22(8) 885-891 (1997)
	CH**	Brayden, D. et al. "Heparin Absorption across the intestin: Effects of Sodium N-[8-2hydorxybenzoyl)Amino] Caprylate in rat in situ intestinal instillations ind in Caco-2 monolayers" Pharmaceutical Research vol 14(12) 1772-1779 (1997)
	CI**	Leone-Bay, A. "Acylated non-alpha-amino acids as novle agents for the oral delivery of heparin sodium, USP" Journal of Controlled Release 50: 41-49 (1998)
	C1	Leone-Bay, A. "4-[4-(2-Hydroxybenzoyl) amino]phenyl]-butyric Acid as Novel Oral Delivery Agent for Recombinant Human Growth Hormone"; Journal of Medicinal Chemistry vol. 39, no. 13 pp 2571-2578 (1996)
	CK**	Leone-Bay, A. "N-Acylated alpha-amino acids as novel oral delivery agents for proteins" "; Journal of Medicinal Chemistry vol 38, 4263-4269 (1995)
	CL**	Leone-Bay, A. "N-Acylated alpha-amino acids as novel oral delivery agents for proteins" "; Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)
	CM**	Ho Koc-Kan; et al. " A Practical Synthesis of ω-aminoalkanoic acid derivatives form Cycloalkanones" Synthetic Communication, vol. 26, no. 14: 2641-2649 (1996)
	CN**	Gurrieri and Siracusa: "Thermal Condensation of Some alpha-aminoacids with Phatalic Acid" Thermochimica Acta, 7 (1973) 231-239
	CO**	Amino Yusuke et al. Chem Pharm Bull 36 pgs 4426-4434 (1988)
	CP**	Brown et al., J. Med. Chem. 27:79-81 (1984)
$\Box$	CQ**	Johansen, Marianne, et al. "The Kinetics of decompn. Of various N-Mannich bases of salicylamide" Int. J. Pharm. (1980), 7(2): 119-27 (1980)
	CR**	Palagiano, F. et al. "Synthesis, stability and anticonvulsant activity of two new GABA prodrugs",» PHARMAZIC, 52(d): 272-276 (1976), XP-001084051
A	CS**	Yalcin, I. et al. "Synthesis and Microbiological Activity of Some Novel N-(2-Hydroxyl-5-Substituted phenyl) Benzaacetatemides, Phenyl acetamides and ThiOphenoxyacetamides as the Possible Metabolites of Antimicrobial Active Benzoxazoles," Il Farmaco, 51(11), 685-681 (1977).

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner Signature Date Considered 76 7					_
	Examiner Signature	Con	14	707	

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

MAY 2 1 2005 E

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1996, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

1	ubstitute for form 1449A/B/PT	o		Complete If Known		
				Application Number	10/750,138-Conf. #9762	
	INFORMATION	I DIS	CLOSURE	Filing Date	December 31, 2003	
	STATEMENT I	BY A	PPLICANT	First Named Inventor	David Gschneidner	
				Art Unit	N/A	
	(Use as many sh	eets as	necessary)	Examiner Name	Not Yet Assigned	
She	1	of	1	Attorney Docket Number	01946/100G527-US2	

U.S. PATENT DOCUMENTS								
Examiner Cit		Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where			
initials*	Cite No. <sup>1</sup>	Number-Kind Code <sup>2</sup> ( # Imown)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear			

			FORE	GN PATENT	DOCUMENTS		
Examiner		Cite	Foreign Patent Document	Publication	Name of Patentee or	Pages, Columns, Lines,	Γ
Initials		No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>8</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	T°
	1	BA	WO-96/12473-A1	05-02-1996	Emisphere Technologies, Inc.	<del> </del>	⇈
		BB	WO-96/12474-A1				$\vdash$
$\Box$		BC	WO-96/12475-A1				Г
4	7	BD	WO-00/07979-A2		Emisphere Technologies, Inc.		┢

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at <a href="https://www.usnic.gov">www.usnic.gov</a> or MPEP 901.04. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Mind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.18 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS							
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	(0	Date	90
Signature	ノしんはリ		1 0 / 6
Signature	000	Considered	10)

<sup>&#</sup>x27;Applicant's unique citation designation number (optional). \*Applicant is to place a check mark here if English language Translation is attached.